REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to highlight the differences between the claimed invention and the cited prior art. Claim 1 has been amended to provide that the motor means comprises a housing and a motor contained within the housing. Support for this amendment is found, for example, at page 11, lines 16-21 and in Figures 1 and 4.

Claim 1 has also been amended to provide for fixedly securing the collar assembly to the housing of the motor means and to reciting that the collar assembly has an opening to allow a screw means to pass therethrough. Connection of the collar assembly to the housing is described at page 12, lines 14-15 and the presence of an opening to allow the screw means to pass therethrough is disclosed at page 12, lines 15-17.

The screw means is now described as having the first end operatively engaged to the motor means as described at page 14, lines 17-20 and as shown best in Figure 4. The second segment of the screw means is operatively engaged to the pivot collar assembly as shown in Figure 4 as described at page 13, lines 9-10 and page 14, lines 20-22.

With reference to the pair of arms described in paragraph b) 3 of claim 1, the second arm segment is now stated to be pivotally attached to the pivot collar

assembly as described at page 13, lines 9-13 referencing Figures 2 and 4. The second arm segments are stated to transverse each other at the pivot collar assembly as shown clearly in Figures 1, 2 and 4. The remaining changes to claim 1 are to provide consistent language with the amendments discussed above. In addition, claim 18 has been amended to recite the distractor arm assembly in the same terms as described in claim 1. Claim 13 has been canceled as essentially redundant of claim 2.

Applicant submits that the amendments made to the claims are consistent with the disclosure and no new matter has been added and entry of the amendment is therefore deemed proper and is respectfully requested.

The specification has also been amended to address the objections set forth at the top of page 2 of the Office Action. No new matter has been added by these changes and the courtesies extended by the Examiner in this regard are greatly appreciated.

The objection to claim 13 also set forth on page 2 has been obviated in view of the cancellation of this claim.

Claims 1-10 and 12-20 stand rejected as obvious over Sherwin (U.S. Patent No. 3,750,652) in view of Brown (U.S. Patent No. 4,899,761). The Office Action states that Sherwin discloses the claimed invention except for the device comprising

the motor means. Brown is stated to teach that it is known to provide a distractor arm assembly with a stepper motor to separate adjacent vertebrae of a motion segment unit. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to modify the device of Sherwin in accordance with Brown. The rejection is hereby traversed and reconsideration is respectfully requested.

Before discussing the prior art, a brief discussion of the present invention in light of the amended claims will be helpful in understanding the significant differences between the claimed invention and that of the prior art.

The present invention is directed to an apparatus and method for measuring instability of a motion segment unit of the spine (comprised of adjacent vertebrae) in which significant damage and/or removal of spinal tissue is reduced or eliminated during the process of making the measurements of the relative stiffness of the spine. The present invention requires a motor means for applying a controllable force and a distractor arm assembly which employs that force to the area of adjacent vertebrae to qualitatively and/or quantitatively measure the relative stiffness of the motion segment unit. The present invention is not directed to a device for separating joints (e.g. a knee) so that surgery can be performed.

There are number of important considerations for employing the device of the present invention. One such consideration is that the size of the incision necessary to make the determination of instability should be as small as possible. Any device

that lacks this consideration is inappropriate for the use intended for the present invention.

Second, the load required to cause the pair of segmented arms to separate and thereby exert a controllable force in the region of a motion segment unit should be as low as possible. In particular, the torque (which is the function of the force applied times the distance between the application of the force and the point of contact with the motion segment unit) should be as low as possible, yet the controllable force must be sufficient to obtain the desired measurements.

Third, the device must be suitable for applying a controllable force having the ability to detect the resistance of the pair of arms to the distraction so that the relative stiffness of the spine can be qualified and/or quantified.

Several key features of the presently claimed invention which meet the unique requirements of measuring the relative stiffness of the spine include a motor means with a housing for applying a controllable force to a distractor arm assembly. A collar assembly is fixedly secured to the housing of the motor means and provides an opening enabling a screw means to pass therethrough. Thus, the collar remains fixed to the housing of the motor means so that when rotational movement is applied to the screw means, the tendency of a distractor arm assembly to rotate is eliminated.

Another important feature of the present invention is the profile of the device shown best in Figure 1. It will be observed that the width of the device between the collar assembly and the ends of the arm segments which contact motion segment unit provides a sleek profile enabling the device to enter the body cavity through as small an incision as possible. This is made possible by having a pivot collar assembly and a pair of segmented arms transversing each other in vicinity of the pivot collar assembly.

The principal reference [Sherwin (U.S. Patent No. 3,750,652)] does not teach or suggest material features of the claimed invention. First, there is no motor means for applying a controllable force to a distractor arm assembly. The reference device is directed to a knee retractor which is employed by a surgeon to operate on a patient's knee through an anterior incision. The purpose of the retractor is to hold the incision open and this is accomplished in the reference device by generally a bow-shaped knee retractor which forcibly effects a distraction of about 1-8th inch in the knee joint without imposing any harmful stresses thereon (column 1, lines 57-68). Thus, it is an essential feature of the reference retractor to provide two non-planar generally bowed retractor arms which are adapted to pivotally open and close by the action of a thumbscrew. As indicated beginning at column 2, line 46, the non-planar bowed shape of the retractor arms is characterized by the lower end portions of arms 11, 12 being outwardly disposed with respect to the upper ends. Each of these lower end portions is also inwardly bent or off-set towards each other.

As shown in Figure 5, the bowed arm arrangement required in the reference has limitations with respect to entering the body cavity. Indeed, the knee retractor disclosed in the reference could not be used for manipulating the spine because the bowed arms would require a much larger incision than would be required in the present invention which employs arms that transverse each other thereby providing a narrow profile to the device.

In addition, it is important to note that the reference device is manipulated by a thumbscrew which is manually operated by the surgeon. Employment of the thumbscrew cannot provide a controllable force to the distractor arm assembly. A controllable force is not necessary because the purpose of the knee retractor is not to measure instability but rather to merely provide sufficient pressure so as to separate parts of the knee joint so that a surgeon can enter the knee to perform surgery.

As previously indicated, the present invention requires a collar assembly fixedly secured to housing of the motor means. It is noted in Figure 5 of the reference that a collar assembly identified by numeral 15 is not fixedly secured to any housing whatsoever let alone a motor means housing. Accordingly, as the thumbscrew is rotated, a part of the rotational force from the turning of the thumbscrew is provided to the collar 15 which provides a rotational moment to the collar. This rotational moment interferes with the ability of a device to measure instability of a motion segment unit. This does not present a problem for the

reference device which is not concerned with measuring instability but merely to separate components of a joint (i.e. the knee). However, the rotational force generated by the thumbscrew cannot be transferred to the distractor arms if an accurate measure of motion segment unit instability is to be determined.

In the device of the present invention, there is provided a pivot collar assembly for engaging the second arm segments so they transverse each other and are pivotally movable with respect to each other. No such pivot collar assembly is provided in the reference device in part because the arms do not transverse each other. The transversing segmented arms of the present invention enable the device to develop a sleek profile which makes it possible to contact motion segment units through a minimally invasive incision. To the contrary, the reference device cannot enter the body cavity through a minimally invasive incision because of the requirement of bowed arms shown best in Figure 5.

The reference device provides a pair of lever arms 18-21 which are operatively engaged to the thumbscrew through an actuating link 25. This mandates a greater load to turn the thumbscrew than in the present invention. In the reference design, the torque required to turn the thumbscrew and distract the knee joint at the location of bone teeth 44, is a function of the "moment arm" which is the distance between points 42 and 44. This distance dictates the amount of torque required to turn the thumbscrew and distract the knee joint. The torque is the force applied times the distance between points 42 and 44. Thus, the reference device would

have to be lengthened considerably in order to fit the device into operative engagement with the spine which exponentially increases the torque required to turn the thumbscrew.

The present invention also provides a collar assembly fixedly secured the motor means which operates totally independent of the screw means. The fixed collar assembly allows the screw means to simply slide up and down through the collar while directly applying the force to the pivot collar assembly where the force is transferred to the second arm segments. This enables more efficient use of force so that constant rate of force can be applied to a motion segment unit.

The position taken in the Office Action that it would have been obvious to provide a stepper motor assembly for the Sherwin device is incorrect. Of particular importance to the claimed invention is the fact that the collar assembly is fixedly secured to the motor means so as to prevent rotational movement to the segmented arms when the screw means is rotated as previously discussed. Furthermore, the screw means has an unthreaded portion which passes through the collar assembly so that no force is applied to the collar assembly. Instead the screw means engages the pivot collar assembly located at the point of transverse of the respective arm segments. To the contrary, the reference device has a threaded portion passing through the collar assembly and therefore provides rotational movement to the arm segments. Accordingly, the present invention is clearly distinguished over Sherwin alone or in combination with Brown. For the same reasons, the claims dependent on

claim 1 either directly or indirectly as well as method claims 18-20 are patentable over the cited references.

Regarding claims 5 and 6, the Office Action states that Sherwin discloses the claimed invention except for the device comprising the means for measuring resistance to the force applied by the motor means based on the disclosure to Brown. This ground of rejection is further traversed because there is no teaching or suggestion in either of the references of how to apply the Brown strain gauges for measuring the resistance to the force applied by the motor means to the Sherwin device which clearly provides no teaching or suggestion of how to use a motor means. Furthermore, the Brown device does not disclose arm segments that transverse each other. Accordingly, there is no teaching of how to incorporate a motor means with the distractor arm assembly of the present invention for achieving the objects thereof.

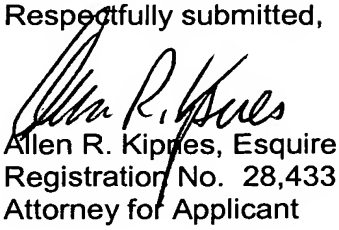
Applicants also object to the rejection of claims 15-17 since there is no teaching or suggestion of a dual leg assembly of the type shown in Figures 9-10. Indeed, the knee distractor of Sherwin has no need for and no basis for a dual leg assembly as required in claims 15-17.

In view of the foregoing, Applicant submits that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

ARK:jsg080906/5081015-016.AMD

It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



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